

CHARGE: 502 (a)—the labeling accompanying the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for gallstones and for cleansing the liver; and 502 (f) (2)—the article was essentially a laxative, and its labeling, while held for sale, failed to warn against use of the article when symptoms of appendicitis are present and failed also to warn that frequent or continued use of the article may result in dependence on laxatives.

DISPOSITION: 1-26-55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4751. Posterior pituitary injection. (F. D. C. No. 37287. S. No. 88-418 L.)

QUANTITY: 44 cartoned vials at Buffalo, N. Y., in possession of Direct Laboratories, Inc.

SHIPPED: 2-24-53, from Chicago, Ill.

LABEL IN PART: (Carton & vial) "No. 2261 10 cc. vial Posterior Pituitary Injection (Surgical) Double U. S. P. strength Each 1 cc. represents: Posterior Pituitary 20 USP units Chlorobutanol 5 mg. (8/100 gr.) * * * Water for injection USP q. s. 1 cc. * * * Administration: Intramuscular or Subcutaneous. * * * Direct Laboratories, Inc. Buffalo 4, New York."

RESULTS OF INVESTIGATION: The article was shipped in bulk, and after its receipt by the consignee, it was repackaged and relabeled. Examination showed that the article contained 73 percent of the declared posterior pituitary potency instead of 85 percent as required by the United States Pharmacopeia.

LIBELED: 10-4-54, W. Dist. N. Y.

CHARGE: 501 (b)—the strength of the article while held for sale differed from the standard for posterior pituitary injection set forth in the United States Pharmacopeia.

DISPOSITION: 11-4-54. Default—destruction.

4752. Chorionic gonadotropin. (F. D. C. No. 37649. S. No. 77-276 L.)

QUANTITY: 99 packages at Philadelphia, Pa.

SHIPPED: 8-16-54, from Los Angeles, Calif.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of chorionic gonadotropin potency.

LIBELED: 2-9-55, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it was represented to possess; and 502 (a)—the label statement "Chorionic Gonadotropin (Lyophilized) 5,000 I. U." was false and misleading.

DISPOSITION: 4-4-55. Default—destruction.

4753. Liver-folic acid B₁₂. (F. D. C. No. 37509. S. No. 89-577 L.)

QUANTITY: 63 vials at Minneapolis, Minn.

SHIPPED: 9-3-54, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Analysis showed the article contained approximately 70 percent of the declared amount of vitamin B₁₂.

LIBELED: 12-9-54, Dist. Minn.

*See also No. 4745.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it purported and was represented to possess, namely, 110 micrograms of vitamin B₁₂ per cubic centimeter; and 502 (a)—the label statement "Each cc. contains: Liver Extract U. S. P. 10 mcgm. Cyanocobalamine. Vit. B₁₂ 100 Mcg." was false and misleading.

DISPOSITION: 1-25-55. Default—destruction.

4754. Chocolated Cokozine. (F. D. C. No. 37631. S. No. 6-629 M.)

QUANTITY: 94 8-oz. btls. and 71 1-pint btls. at Cincinnati, Ohio.

SHIPPED: Between 1943 and 1950, from New York, N. Y.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of vitamin B₁.

LIBELED: 1-31-55, S. Dist. Ohio.

CHARGE: 501 (c)—the strength of the article while held for sale differed from that which it was represented to possess, namely, 10 milligrams of vitamin B₁ (thiamine hydrochloride) per fluid ounce; and 502 (a)—the label statement "Contains in One Fluid Ounce: * * * Thiamin hydrochloride. . . . 10 mg." was false and misleading.

The libel alleged also that two other articles, namely, thiamine chloride elixir and malt syrup with halibut liver oil, were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 3-3-55. Default—destruction.

4755. Rauwolfia serpentina. (F. D. C. No. 37594. S. Nos. 11-927/8 M.)

QUANTITY: 1 barrel containing 86 lbs. and 2 100-lb. drums at Brooklyn, N. Y.

SHIPPED: (2-drum lot) 4-19-54, from Tuticorin, India, by J. M. L. Danusu & Co.; (1-barrel lot) 5-4-54, from Chicago, Ill., by Armour Laboratories.

LIBELED: 1-12-55, E. Dist. N. Y.

CHARGE: 501 (d) (2)—the article in each lot was represented as *Rauwolfia serpentina*, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part therefor when shipped; 502 (a)—the label designations (1-barrel lot) "Rauwolfia Serpentina" and (2-drum lot) "Pow. Rauwolfia Serpentina" were false and misleading since such designations represented and suggested that the article in each lot consisted wholly of *Rauwolfia serpentina*, which was not the case; and 502 (i) (3)—the article in each lot was offered for sale under the name of another drug.

DISPOSITION: 3-9-55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4756. Testo-Glan Male Formula and Fem-Tone Female Formula. (Inj. No. 275.)

COMPLAINT FOR INJUNCTION FILED: 3-9-54, E. Dist. N. Y., against Leo Shine, t/a Glanex Products, Floral Park, N. Y.

LABEL IN PART: "Testo-Glan Male Formula Regular Strength Each capsule contains—Hormonal activity as found in wheat—Testosterone (Male Sex Hormone) 0.067 mcg. Vitamin E 0.034 mgms. Survival Factor + Vitamin B 1 5 mg. 500% MDR Vitamin B 2 3.5 mg. 175% MDR Niacinamide 15 mg. [or "Double Strength Each capsule contains—

*See also Nos. 4741, 4742, 4746, 4750, 4752-4755.